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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,281	09/09/2004	Sanford Reich	642P003-US	9199

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,281	REICH ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/28/04* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

2. Applicant's arguments, see Remarks, filed April 7, 2008, with respect to the rejection(s) of claim(s) 1-3, 6 and 11 under 35 U.S.C. 102 and claims 4, 5 and 7-10 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references.

Drawings

3. After further review of the drawings as originally filed, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first and second drainage paths must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Specifically, Fig. 1 shows the first path and second path as separate, one having a variable check valve and one being a passive low resistance path with no valve present. However, Fig. 1 is a schematic. Applicant discloses alternate embodiments of the variable check valve in Figs. 2 and 6. However, the claims recite a variable check valve that is only present in the second path. Figs. 2 and 6 appear to show only one possible path that cerebrospinal fluid is routed through when entering the disclosed controller, that path having both the check valve and the bistable latching valve present, when it

is disclosed in Fig. 1 and in the specification that the bistable latching valve routes the fluid coming through inlet cannula 15 to either a path with the variable check valve (the claimed second path) or a path without it (the claimed first path).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Madsen et al (U.S. Patent No. 6,383,160).

With respect to **claim 1:** Madsen teaches a system for regulating the flow of cerebrospinal fluid (hereafter, "CSF") from the brain of an individual comprising an implantable controller in the form of anti-siphon shunt valve 80 adapted to be in fluid communication with said CSF and having first and second drainage paths 86 and 88, respectively, wherein said controller 80 directs the flow of said cerebrospinal fluid into said first or second drainage paths in response to the inclination of said individual. (Fig. 10, Col. 6, lines 17-27) This direction of flow in response to inclination of the individual as taught by Madsen is accomplished via a closed-loop feedback control system wherein orientation sensor 104 that provides data on the orientation of the housing to determine if the patient is recumbent or vertical sends said data as an input to controller 106, which in turn sends control signals to actuator 108 which adjusts the height of an adjustable barrier 38 which in turn applies pressure to a ball valve that seats against the pathway 88, directing flow into pathway 86. (Fig. 12, Col. 7, lines 6-17) Hereafter in this Office action, the controller 106 taught by Madsen will be referred to as "control 106" to avoid confusion and distinguish the controller from controller 80 previously established in this action. The entire feedback system is *in vivo*, implanted within the housing of the anti-siphon shunt valve 80. Thus, the controller 80, including the feedback system therein, directs the flow of said CSF into said first or second drainage paths 86 or 88 in response to the inclination of the individual. (Col. 7, lines 18-23)

With respect to **claim 2:** The first drainage path 86 is a supine flow path inasmuch as Madsen teaches that this is a path of least resistance through which CSF flows when the patient is recumbent, i.e. supine. (Col. 6, lines 37-43) The controller 80 directs the flow of said fluid into said supine flow path when said individual's inclination is supine or substantially supine inasmuch as Madsen teaches that data provided from orientation sensor 104 as to whether the patient is recumbent or vertical is provided to control 106, which sends signals to actuator 108 to adjust the adjustable barrier accordingly to provide optimal drainage conditions for the patient according to the inclination of the user, wherein sensor 104, control 106 and actuator 108 are integral to the controller 80. (Col. 6, lines 6-17)

With respect to **claim 3:** The second drainage path 88 is an upright flow path inasmuch as Madsen teaches that when the patient stands up (or sits up), the anti-siphon valve 10 exhibits a high fluid flow resistance that is greater than the resistance of high-resistance valve 90, thus forcing valve 90 open to allow drainage of fluid through second pathway 88 to outlet 94. (Col. 6, lines 43-52) The controller 80 directs the flow of said fluid into said upright flow path when said individual's inclination is vertical or substantially vertical inasmuch as Madsen teaches that data provided from orientation sensor 104 as to whether the patient is recumbent or vertical is provided to controller 106, which sends signals to actuator 108 to adjust the adjustable barrier accordingly to provide optimal drainage conditions for the patient according to the inclination of the user, wherein sensor 104, control 106 and actuator 108 are integral to the controller 80. (Col. 6, lines 6-17)

With respect to **claim 4:** The system taught by Madsen further comprises an inclination sensor in the form of orientation sensor 104 for sensing the inclination of said individual by sensing the

inclination of the shunt valve housing. (Col. 6, lines 6-17) The controller 80 is responsive to said inclination sensor 104 inasmuch as the data sent from sensor 104 is processed by a control 106 which then sends a signal to actuator 108 to adjust the barrier 38 of the valve 10 to provide optimal drainage conditions for the patient, and sensor 104, control 106 and actuator 108 are all structural elements of controller 80.

With respect to **claim 5:** The system further comprises a bi-stable latching valve in the form of anti-siphon valve 10 comprising a rotatable magnet actuated by remote device 56 that causes rotation of a rod 48 that adjusts the height of an adjustable barrier 36 that seats in and blocks a fluid pathway if desired. The rotating magnet, rod, barrier and externally applied magnetic field collectively constitute a bistable latching valve inasmuch as the rotatable magnet is a stepping motor as taught by reference to U.S. Patent No. 4,595,390 to Hakim et al and thus Madsen teaches a stepping motor, rod, barrier and externally applied magnetic field. (Col. 5, lines 18-30) The stepping motor, rod, and barrier or platform are all structural elements disclosed by applicant in Figs. 1 and 2 as constituting the claimed bistable latching valve. (Specification, (Page 11, line 30 – Page 12, line 6) Both the claimed bistable valve and the antisiphon valve 10 of Madsen are bistable because they are able to automatically open without any external force applied to relieve fluid pressure by allowing drainage. For clarification, in Fig. 2 and as disclosed by applicant on Page 11, paragraph 2 of the specification, the variable spring length check valve is comprised of the sapphire ball 52 and its biasing element, the spring 53. The bistable valve, in series with the check valve as indicated in Fig. 1, is comprised of the rotating nut 55 driven by a stepping motor (not shown), the rod 56 and the adjustable platform or barrier 57. (Specification, Page 11, line 30 – Page 12, line 6) The controller 80 directs the flow of said fluid by actuating

said latching valve via actuator 108 that adjusts the height of barrier 38 to allow for fluid communication with said first or said second drainage paths 86, 88, respectively.

With respect to **claim 6:** The supine flow path 86 taught by Madsen comprises a passive low resistance flow path inasmuch as Madsen teaches that CSF flows through path 86 with little or no resistance under normal circumstances when the patient is recumbent/supine. (Col. 6, lines 37-43)

With respect to **claim 7:** Madsen teaches by reference to U.S. Patent No. 4,595,390 to Hakim et al an anti-siphon valve that is present in pathway 86, the passive low resistance flow path, that has an adjustable closing pressure adjustable to any pressure between 20-190 mm H_2O (1.5-14.0 mm Hg) which would necessarily serve as the maximum intraventricular pressure of the CSF flowing therethrough. ('390, Col. 10, lines 14-33) A CSF intraventricular pressure beyond the closing pressure would cause closure of the anti-siphon valve. Since a closing pressure of 15 mm Hg falls within the range taught by Hakim, Madsen by reference to Hakim anticipates the limitation "wherein said passive low resistance flow path maintains a maximum intraventricular pressure of about 15 mm Hg".

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al ('160).

With respect to **claim 8:** The system taught by Madsen further comprises a programmable variable check valve in the form of high resistance valve 90 that can be preset to a particular opening pressure. (Col. 6, lines 53,54) Valve 90 is in said second flow path 88 (Fig. 10). Madsen teaches that control 106 can be implemented by a microprocessor which is implanted within the housing to perform all measurement and control functions. (Col. 7, lines 18-21) Madsen also teaches that the valve 90 can be a diaphragm (Col. 6, line 56) and teaches an alternate embodiment of the anti-siphon valve 10 that has a barrier 36 (identical to barrier 38 in the embodiment of Fig. 10) that is acted upon by a diaphragm 32. (Col. 3, lines 22-30) Therefore, Madsen teaches an alternate embodiment of the barrier 32, barrier 36, is actuated by actuator 108 whose movement is controlled by control 106 in response to data from inclination sensor 104 regarding the inclination angle of the individual.

Madsen does not disclose a single embodiment in which the opening (i.e. cracking) pressure of said check valve 90 is modified based on the inclination angle of said individual. However, it would be obvious to one of ordinary skill in the art to modify the device of Madsen so as to create a single embodiment wherein wherein the cracking pressure of said checking valve is modified based on the inclination angle of said individual as an alternate means for programming the programmable check valve to effect proper drainage of CSF to relieve

intracranial pressure. The adjustment of the barrier in the device suggested by Madsen would be actuated by a second actuator identical to actuator 108 whose movement would also be controlled by control 106 upon receipt and processing of data regarding the inclination angle of the individual from inclination sensor 104. The device fairly suggested by Madsen thus renders the limitation "wherein the cracking pressure of said checking valve is modified based on the inclination angle of said individual" obvious.

With respect to **claim 9:** The opening/cracking pressure of programmable variable check valve 90 suggested by Madsen is continually modified by second actuator 108 acting on signals from control 106, which is in turn is acting on data from inclination sensor 104 regarding the current inclination angle of the individual. (Col. 7, lines 6-17) With regard to the limitation "to maintain a relatively stable intraventricular pressure for a range of inclination angles", the device fairly suggested by Madsen meets all of the claim limitations as to a programmable variable check valve having a cracking pressure that is continually modified based on the inclination angle of the individual, and a maximum intraventricular pressure as disclosed and claimed is maintained by the device (see the rejection of claim 10). Therefore, the device fairly suggested by Madsen necessarily maintains a stable intraventricular pressure for a range of inclination angles.

With respect to **claim 10:** Madsen teaches by reference to '390 to Hakim that the anti-siphon device can be set at any closing pressure between 20-190 mm H_2O (1.5-14.0 mm Hg) ('390, Col. 10, lines 14-33), which would act as the maximum intraventricular pressure prior to closing of the valve. Madsen also teaches a closing pressure for valve 90, beyond which the CSF which would create additional intraventricular pressure (hereafter "IVP") and backup in path 86. Madsen does not teach that the stable intraventricular pressure is between 5 mm Hg and -5 mm

Hg. It would be obvious to modify the device of Madsen such that the stable intraventricular pressure is below the maximum intraventricular pressure equal to closing pressure of the antisiphon valve to prevent backup into pathway 86. Madsen also fairly suggests continually modifying the cracking pressure to maintain a relatively stable intraventricular pressure by suggesting a device in which the cracking pressure of valve 90 is modified by adjusting barrier 36 according to the inclination of an individual. Therefore Madsen suggests a stable intraventricular pressure that is equal to the closing pressure of the anti-siphon valve, i.e. between 1.5 – 14.0 mm Hg and equal to the cracking pressure of the check valve to maintain a stable intraventricualr pressure without exceeding the maximum, causing backup in path 86 and potential overdrainage by exceeding the cracking pressure of valve 90, opening said valve 90. This range for stable intraventricular pressure fairly suggested by Madsen overlaps and renders obvious the claimed range for stable intraventricular pressure of between 5 to -5 mm Hg.

With respect to **claim 11:** The controller 80 implanted in said individual further comprises an inlet connection 92, an outlet connection 94 spaced from said inlet connection 92 (Col. 6, line 23), and an inlet cannula in the form of inlet tubing 22 with a distal and proximal end, wherein said distal end of said inlet cannula is located near the ventricle of the brain and said proximal end of said inlet cannula is connected to said inlet connection 92 of said controller 80. The controller 80 also comprises an outlet cannula in the form of outlet tubing 24 with a distal and proximal end. The proximal end of said outlet cannula 24 is connected to said outlet connection 94 of said controller 80. (Col. 3, lines 40-50)

Madsen does not explicitly teach that the location of said distal end of said outlet cannula 24 is any of the peritoneal space and the right atrium of the heart. However Madsen discloses that it is known in the art to treat hydrocephalus, caused by excess intracranial

pressure due to excess CSF fluid adjacent the brain, by using a fluid shunt system to drain excess CSF from the cerebral ventricles to the peritoneal cavity/space. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Madsen such that the location of the distal end of the instant outlet cannula is the peritoneal space with a reasonable expectation of success to provide a means to treat hydrocephalus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761